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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,060	08/21/2001	Anthony Louis Devico	4115-144 CIP	8085

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,060

Applicant(s)

DEVICO ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 13.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a chimeric polypeptide, classified in class 424, subclass 185.1.
- II. Claim 17-22, drawn to a polynucleotide encoding a chimeric polypeptide, classified in class 536, subclass 23.4.
- III. Claims 23-33, drawn to an antibody that binds the chimeric polypeptide , classified in class 530, subclass 389.1.
- IV. Claims 34-35, 39-44, drawn to a method of producing an antibody to the chimeric polypeptide, classified in class 435, subclass 7.1.
- V. Claims 36-38, drawn to a method of inhibiting viral infection in a human subject polypeptide, classified in class 435, subclass 5.
- VI. Claims 45-51, drawn to a method of identifying an agent that inhibits the interaction between a virus and a co-receptor, classified in class 435, subclass 4.
- VII. Claims 52-54, drawn to a method of identifying a chimeric polypeptide that inhibits viral infection, classified in class 424, subclass 185.

For each invention of groups I, III and IV above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects one of the inventions of groups I, III or IV, election is further required for one of inventions (A)-(I).

- (A). SEQ ID NO: 13 comprises SEQ ID NO: 28 (HIV) and 26.
- (B). SEQ ID NO: 2 comprises SEQ ID NO: 24 (HIV) and 26.
- (C). SEQ ID NO: 4 comprises SEQ ID NO: 30 (HIV) and 26.

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- (D). SEQ ID NO: 6 comprises SEQ ID NO: 30 (HIV) and 20.
- (E) SIV
- (F) FIV
- (G) FeLV
- (H) FPV
- (I) herpes virus

For each invention of groups V and VII above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects one of the inventions of groups V or VII, election is further required for one of inventions (A)-(D).

- (A). SEQ ID NO: 13 comprises SEQ ID NO: 28 (HIV) and 26.
- (B). SEQ ID NO: 2 comprises SEQ ID NO: 24 (HIV) and 26.
- (C). SEQ ID NO: 4 comprises SEQ ID NO: 30 (HIV) and 26.
- (D). SEQ ID NO: 6 comprises SEQ ID NO: 30 (HIV) and 20.

For each invention of group II above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects the inventions of group II, election is further required for one of inventions (J)-(R).

- (J). SEQ ID NO: 12 comprises SEQ ID NO: 27 and 25.
- (K). SEQ ID NO: 1 comprises SEQ ID NO: 23 and 25.
- (L). SEQ ID NO: 3 comprises SEQ ID NO: 29 and 25.
- (M). SEQ ID NO: 5 comprises SEQ ID NO: 29 and 19.
- (N) SIV
- (O) FIV
- (P) FeLV
- (Q) FPV
- (R) herpes virus

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(I) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for antibody interaction and as an immunogen, the different sequences have different effects.

Inventions (J)-(R) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polynucleotides encoding different polypeptides. Therefore, where structural identity is required, such as for antibody interaction and as an immunogen, the different sequences have different effects.

Groups I-III are compositions and are distinct from groups IV-VII which are drawn to methods. Groups I-III are compositions and each is distinct from the other because they contain different materials. Group I comprises a chimeric polypeptide which is made up of amino acids. Group II comprises the DNA sequence for the chimeric protein; and DNA is made up of nucleic acids. Group III comprises an antibody to the chimeric protein, although antibodies themselves are proteins, they are different molecules with different structures. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group.

Groups IV-VII are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not expected to be the same.

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Groups IV is drawn to a method of producing an antibody by administering a chimeric polypeptide. Group V is drawn to a method of inhibiting viral infection in a human subject. Group VI is drawn to a method of identifying an agent that inhibits the interaction between a virus and a co-receptor. Group VII is drawn to a method of identifying a chimeric protein that inhibits a viral infection. Though there may be overlap between these methods in question for groups IV-VII, each utilizes different materials and therefore the outcome is expected to be different.

Claim 1 link(s) inventions A-I. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 4 [SEQ ID NO: 26] link(s) inventions A-C. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 4 [SEQ ID NO:

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26]. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 3 [SEQ ID NO: 30] link(s) inventions C-D. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 3 [SEQ ID NO: 30]. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are

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no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971).

See also MPEP § 804.01.

Claim 17 link(s) inventions J-R. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antibodies can be used to prevent viral infection in a subject.

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Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inhibition of a viral infection can be achieved with an antibody to the viral receptor.

Inventions IV and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case antibodies can be made recombinantly.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D. 7/2/03
PATENT EXAMINER